Attorney's Docket No.: 12.009011 DIV In re: Hung

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 8 of 22

Remarks/Arguments

Claims 27-60 were originally pending. Claims 27-60 have been re-numbered as claims

1-34 as per the Examiner's request. Claims 1-34 are currently pending. Claims 1-34 have been

rejected.

Rejection of Claims 1-5, 7, 9-17, 19, 21 and 22 Under 35 U.S.C. 103(a)

The Examiner states that claims 1-5, 7, 9-17, 19, 21 and 22 have been rejected under 35

U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,838,862 (Baker et al.) in view of

U.S. Patent No. 5,763,415 (Sukamar et al.) and Bolivar et al. (Acta Radiologica, March 1997,

Vol. 38, pp. 240-242). Specifically, the Examiner states that:

Baker et al. discloses a small portable osmotic pump which fulfills the specific

embodiment of claim 3. Baker et al. does not teach the specific configuration required for

support on a nipple, nor an elongated member for delivering agent into a breast duct. Sukumar et

al. teaches the localized treatment of a mammary gland comprising contacting the ductal

epithelium with an anti-cancer agent via ductal cannulation. Bolivar teaches the use of a Kopans

guide for an anchor within mammary ducts. Therefore it would have been prima facie obvious at

the time the invention was made to configure the small osmotic pump of Baker to be supported

on a nipple, and to use a cannula to protrude from the breast and the Kopans guide to position the

cannula at an intraductal lesion.

Applicants respectfully traverse the foregoing rejection on the grounds that the Examiner

has failed to establish a prima facie case of obviousness, since Baker et al., Sukamar et al., and

Bolivar et al. alone or in combination, fail to teach or suggest the claimed invention and further

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 9 of 22

fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

A new combination of elements can be patented "whether it be composed of elements all new, partly new or all old." *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

"[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." Dembiczak, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art

Attorney's Docket No.: 12.009011 DIV

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 10 of 22

In re: Hung

"conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkinstyle trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." Sibia Neurosciences, Inc. v. Cadus Pharma. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg., Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," <u>Clearstream Wastewater Sys. v. Hydro-Action, Inc.</u>, 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." <u>Panduit Corp. v. Dennison Mfg. Co.</u>, 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); <u>Arkie Lures, Inc. v. Gene Larew Tackle, Inc.</u>, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 11 of 22

The motivation cited in the present Office Action (page 5, third paragraph) for the proposed combination is as follows:

"One of skill in the art would have been motivated to do so by the teachings of Sukumar *et al.* on the intraductal administration of chemotherapeutic agents and the teachings of Bolivar *et al.* on the relative accessibility of intraductal lesions and the anchoring of a guide within the breast. One of skill in the art would have been motivated to keep the cannula correctly placed during the treatment."

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required under In re Dembiczak. The claims here are no more obvious than those at issue in Dembiczak. No clear, particular suggestion or motivation in the prior art to make the specific combination of a "device for delivering an agent to a breast milk duct over time, said device comprising: a unit for holding the agent to be delivered to the breast duct, said unit being sized and configured to be positioned and supported on a nipple, and an elongated member for delivering the agent from the unit to the breast duct, said elongated member being in communication with said unit, being sized for positioning within the breast duct, and having a distal terminal end for positioning within the breast duct, said distal end having an atraumatic tip" as recited in claim 1 has been provided, much less for the claims dependent thereon with their additional limitations.

First, there is no teaching or suggestion in Baker *et al*. for using or modifying the disclosed pump for use with administering agents to a breast duct. Baker *et al*. teaches a "portable controlled release osmotic infusion pump which can be activated quickly and simply on demand" that can be "stored, complete with drug and pump activating fluid, for prolonged periods without deterioration." (column 2; lines 43-46). In particular, Baker *et al*. describes pumps which are useful in "medical emergencies such as attack by toxic agents in warfare or

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 12 of 22

severe allergic reactions." (column 2; lines 35-40). There is no mention Baker *et al.* that the pumps could or should be used to deliver agents (e.g., chemotherapeutics) to a breast duct over an extended period of time. Likewise, there is no teaching or suggestion in Sukumar *et al.* or Bolivar *et al.* of administering agents to a breast duct via an externally positioned pump.

Second, Sukumar *et al.* does not teach or suggest the use of the delivery of an agent to a breast duct over time. As demonstrated by Examples 1, 4, 5 and 8 in Sukumar *et al.*, delivery of agents to breast ducts was accomplished by a single injection. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the method of Sukumar *et al.* does not require continuous application of an agent via an osmotic pump as described in Baker *et al.* 

Lastly, Bolivar et al. does not teach or suggest the anchoring of an elongated member in a breast duct. Bolivar et al. teaches the use of a Kopans guidewire for marking the location of ductal growths. Bolivar et al. does not teach or suggest a device comprising a unit for holding an agent to be delivered to a breast duct, the unit being sized and configured to be positioned and supported on a nipple, with an elongated member for delivering the agent from the unit to the breast duct, the elongated member being in communication with the unit and includes a portion for securely maintaining the elongated member within the breast duct by a protruding member for engaging a wall of the breast duct. The elongated member in the present invention has a protruding member which engages the wall of the breast duct. The elongated member is also used to deliver agent from the unit to the breast duct (e.g., a cannula). Bolivar et al. does not teach an elongated engaging member that can deliver an agent. Bolivar et al. merely teaches the use of a Kopans guidewire which cannot function as an elongated member to deliver an agent to

Appl. No.: 10/721,701

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 13 of 22

a breast duct. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the device of Bolivar *et al.* is not used for the administration of agent to a breast duct, and the cannula described in Sukumar *et al.* has no need to be anchored in place because, as explained previously, the agent administered in Sukumar *et al.* is via single injection.

Prima facie obviousness has not been established under such conditions. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

## Rejection of Claims 23-32 Under 35 U.S.C. 103(a)

The Examiner states that claims 23-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,845,770 (Theeuwes *et al.*) in view of U.S. Patent No. 5,763,415 (Sukamar *et al.*) and Bolivar *et al.* (Acta Radiologica, March 1997, Vol. 38, pp. 240-242). Specifically, the Examiner states that:

Theeuwes *et al.* teaches an implantable drug delivery device shaped like a bullet for providing neoplastic agents. Theeuwes *et al.* teaches that the device will provide 0.001cc to 5cc fluid per hour, day or longer. It would have been prima facie obvious at the time the invention was made to configure a bullet shaped dwelling osmotic pump for positioning within a breast duct, said implantable pump having a tether which extends out of the breast duct for removal.

Applicants respectfully traverse the foregoing rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness, since Theeuwes *et al.*, Sukamar *et al.*,

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 14 of 22

and Bolivar *et al.* alone or in combination, fail to teach or suggest the claimed invention and further fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

To establish a prima facie case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in making the claimed invention. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)). Moreover, when a combination of references are used to establish a prima facie case of obviousness, the Examiner must present evidence that one having ordinary skill in the art would have been motivated to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. See, e.g., Carella v. Starlight Archery, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and Ashland Oil, Inc. v. Delta Resins and Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

The motivation cited in the present Office Action (page 6, fourth paragraph) for the proposed combination is as follows:

"One of skill in the art would have been motivated to do so by the teachings of Sukumar et al. on the localized delivery of antineoplastic drugs to breast epithelium and the teachings of Bolivar et al. about the Kopans guide for positioning a wire within a breast duct. One of skill in the art would have been motivated to position the implantable pump at the correct location via the Kopans guide so as to provide the most efficacy in the local treatments and to have a pump which would be removed when depleted and replaced with a filled device."

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 15 of 22

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required under *Carella* and *Ashland Oil*. Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to create a device for delivering an agent to a breast milk duct over time, said device comprising: a unit for holding the agent to be delivered to the breast duct, said unit being sized and configured to be positioned and supported on a nipple, and an elongated member for delivering the agent from the unit to the breast duct, said elongated member being in communication with said unit, being sized for positioning within the breast duct, and having a distal terminal end for positioning within the breast duct, said distal end having an atraumatic tip as recited in claim 1, much less for the claims dependent thereon with their additional limitations.

There is no teaching or suggestion in Theeuwes *et al*. for using or modifying the disclosed pump for use with administering agents to a breast duct. Theeuwes *et al*. teaches a drug delivery device to effectively meter a drug to the eye or to a uterine cavity (see Figures 4-8). There is no mention in Theeuwes *et al*. that the disclosed pumps could or should be used to deliver agents to a breast duct over an extended period of time. The Examiner states that Theeuwes *et al*. teaches a pump "...for providing neoplastic agents. (page 6; second paragraph). The Applicants disagree. Theeuwes *et al*. cannot be considered an enabling disclosure for the administration of chemotherapeutic agents to a breast duct. Theeuwes *et al*. merely lists a number of categories of compositions which may be administered by an osmatic dispensing device such as hypnotics, sedatives, psychic energizers, tranquilizers, anticonvulsants, muscle

Appl. No.: 10/721,701 Filed: November 25, 2003

agents described in Sukamar et al.

Filed: November 25, 20 Page 16 of 22

relaxants, analgesics, anti-inflammatory, anesthetics, anti-spasmodics, anti-ulcer agents, anti-microbials, hormonal agents, cardiovascular agents, diuretics, and neoplastic agents. The only example that Theeuwes *et al.* provides in the specification for actual treatment of a disease in a human is for the continued release of the ocular drug pilocarpine nitrate for the treatment of glaucoma (Example 1). Pilocarpine nitrate is not a neoplastic agent. Since Theeuwes *et al.* does not teach or suggest the administration of a chemotherapeutic agent to a breast duct, one skilled in the art would not have been motivated to combine the pump of Theeuwes *et al.* to deliver the

As mentioned previously, Sukumar *et al.* does not teach or suggest the use of the delivery of an agent to a breast duct over time. As demonstrated by Examples 1, 4, 5 and 8 in Sukumar *et al.*, delivery of agents to breast ducts was accomplished by a single injection. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the method of Sukumar *et al.* does not require continuous application of an agent via an osmotic pump as described in Theeuwes *et al.* 

Finally, as mentioned previously, Bolivar *et al.* does not teach or suggest the anchoring of an elongated member in a breast duct. Bolivar *et al.* teaches the use of a Kopans guidewire for marking the location of ductal growths. Bolivar *et al.* does not teach or suggest a device comprising a unit for holding an agent to be delivered to a breast duct, the unit being sized and configured to be positioned and supported on a nipple, with an elongated member for delivering the agent from the unit to the breast duct, the elongated member being in communication with the unit and includes a portion for securely maintaining the elongated member within the breast duct by a protruding member for engaging a wall of the breast duct. The elongated member in

Appl. No.: 10/721,701

Filed: November 25, 2003

Page 17 of 22

the present invention has a protruding member which engages the wall of the breast duct. The elongated member is also used to deliver agent from the unit to the breast duct (e.g., a cannula). Bolivar *et al.* does not teach an elongated engaging member that can deliver an agent. Bolivar *et al.* merely teaches the use of a Kopans guidewire which cannot function as an elongated member to deliver an agent to a breast duct. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the device of Bolivar *et al.* is not used for the administration of agent to a breast duct, and the cannula described in Sukumar *et al.* has no need to be anchored in place because, as explained previously, the agent administered in Sukumar *et al.* is via single injection.

Prima facie obviousness has not been established under such conditions. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

## Rejection of Claims 1-3, 6, 8-15, 18, 20-28, 31, 33 and 34 Under 35 U.S.C. 103(a)

The Examiner states that claims 38-46 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,797,898 (Santini *et al.*) in view of U.S. Patent No. 5,763,415 (Sukamar *et al.*) and Bolivar *et al.* (Acta Radiologica, March 1997, Vol. 38, pp. 240-242). Specifically, the Examiner states that:

Santini *et al.* teaches small implantable microchip devices that function as drug dispensing agents. Santini *et al.* also teaches that for in vivo applications the entire device is encapsulated in a biocompatible material and can be implanted into a patient by injection.

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 18 of 22

Applicants respectfully traverse the foregoing rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness, since Santini *et al.*, Sukamar *et al.*, and Bolivar *et al.* alone or in combination, fail to teach or suggest the claimed invention and further fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

To establish a prima facie case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in making the claimed invention. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)). Moreover, when a combination of references are used to establish a prima facie case of obviousness, the Examiner must present evidence that one having ordinary skill in the art would have been motivated to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. See, e.g., Carella v. Starlight Archery, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and Ashland Oil, Inc. v. Delta Resins and Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

The motivation cited in the present Office Action (page 8, fourth paragraph) for the proposed combination is as follows:

"One of skill in the art would have been motivated to do so by the teachings of Sukumar *et al.* on the localized delivery of antineoplastic drugs to breast epithelium

Attorney's Docket No.: 12.009011 DIV

In re: Hung

Appl. No.: 10/721,701

Filed: November 25, 2003

Page 19 of 22

and the teachings of Bolivar et al. about the Kopans guide for positioning a wire within a breast duct. One of skill in the art would have been motivated to position the implantable pump at the correct location via the Kopans guide so as to provide the most efficacy in the local treatments and to have a pump which would be removed when depleted and replaced by a filled microchip."

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required under *Carella* and *Ashland Oil*. Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to create a device for delivering an agent to a breast milk duct over time, said device comprising: a unit for holding the agent to be delivered to the breast duct, said unit being sized and configured to be positioned and supported on a nipple, and an elongated member for delivering the agent from the unit to the breast duct, said elongated member being in communication with said unit, being sized for positioning within the breast duct, and having a distal terminal end for positioning within the breast duct, said distal end having an atraumatic tip as recited in claim 1, much less for the claims dependent thereon with their additional limitations.

The Examiner states that it would have been prima facie obvious at the time the invention was made to configure a bullet shaped indwelling microchip reservoir for positioning within a breast duct. The Applicants disagree.

First, there is no teaching or suggestion in Santini *et al.* for using or modifying the disclosed microchip for use with administering agents to a breast duct. There is no mention in Santini *et al.* that the microchip drug delivery device can be sized and configured to be positioned and supported on a nipple.

Appl. No.: 10/721,701 Filed: November 25, 2003

Page 20 of 22

In particular, the specification in Santini *et al.* provides no description of the size or shape of the microchip. In fact, the limitations of the present claims (3, 15, and 28) require a reservoir sized to hold a volume of the agent in the range of from about 0.001 ml to 10 ml. Santini *et al.* describes a microchip that has a thickness of "...approximately 10µm to several millimeters." (column 3, lines 29-31). Since one milliliter (1ml) is equal to 1000 cubic millimeters, it is physically impossible that the microchip describes in Santini *et al.* could have a reservoir sized to hold a volume of an agent anywhere close to 1ml. Since Santini *et al.* either alone or in combination with Sukumar *et al.* and Bolivar *et al.* does not contain all of the limitations of the present claims, prima facie obviousness has not been established under such conditions. For this reason, withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

Second, since Santini et al. does not teach or suggest the administration of an agent to a breast duct, one skilled in the art would not have been motivated to combine microchip drug delivery device of Santini et al. to deliver the agents to a breast duct as described in Sukamar et al. As mentioned previously, Sukumar et al. does not teach or suggest the use of the delivery of an agent to a breast duct over time. As demonstrated by Examples 1, 4, 5 and 8 in Sukumar et al., delivery of agents to breast ducts was accomplished by a single injection. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the method of Sukumar et al. does not require continuous application of an agent via an osmotic pump as described in Santini et al.

Finally, as mentioned previously, Bolivar *et al.* does not teach or suggest the anchoring of an elongated member in a breast duct. Bolivar *et al.* teaches the use of a Kopans guidewire for marking the location of ductal growths. Bolivar *et al.* does not teach or suggest a device

Appl. No.: 10/721,701

Filed: November 25, 2003

Page 21 of 22

comprising a unit for holding an agent to be delivered to a breast duct, the unit being sized and configured to be positioned and supported on a nipple, with an elongated member for delivering the agent from the unit to the breast duct, the elongated member being in communication with the unit and includes a portion for securely maintaining the elongated member within the breast duct by a protruding member for engaging a wall of the breast duct. The elongated member in the present invention has a protruding member which engages the wall of the breast duct. The elongated member is also used to deliver agent from the unit to the breast duct (e.g., a cannula). Bolivar *et al.* does not teach an elongated engaging member that can deliver an agent. Bolivar *et al.* merely teaches the use of a Kopans guidewire which cannot function as an elongated member to deliver an agent to a breast duct. Thus, one having ordinary skill in the art would not have been motivated to make the claimed invention because the device of Bolivar *et al.* is not used for the administration of agent to a breast duct, and the cannula described in Sukumar *et al.* has no need to be anchored in place because, as explained previously, the agent administered in Sukumar *et al.* is via single injection.

Prima facie obviousness has not been established under such conditions. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

In re: Hung

Appl. No.: 10/721,701

Filed: November 25, 2003

Page 22 of 22

Attorney's Docket No.: 12.009011 DIV

Conclusion

In light of the arguments presented above, Applicants respectfully submit that the claims

are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required,

beyond those that may otherwise be provided for in documents accompanying this paper.

However, in the event that additional extensions of time are necessary to allow consideration of

this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit

Account No. 502855 referencing attorney docket number 12.009011.

Respectfully submitted,

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